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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,152	06/15/2001	Giulia Kennedy	097268061663.002	8227

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EXAMINER	
SAKELARIS, SALLY A	

ART UNIT	PAPER NUMBER
1634	6

DATE MAILED: 11/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/883,152	KENNEDY ET AL.	
	Examiner	Art Unit	
	Sally A Sakelaris	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 12, 13, and 21 are drawn to a method for detecting a cancerous colon cell using polynucleotides, classified in class 435, subclass 6.

II. Claim 3, drawn to a method for detecting a cancerous colon cell using a polypeptide, classified in class 435, subclass 7.1.

III. Claims 4 and 5 drawn to a method for detecting a cancerous colon cell using an array, classified in Class 435, subclass 6.

IV. Claims 6, 7, and 8 drawn to a method of identifying a cancerous colon cell by detecting a differentially expressed polypeptide in an array format, classified in Class 530, subclass 350.

V. Claims 9, 10, and 11, drawn to a method of detecting differentially expressed gene product in a test cell indicating whether or not the test cell is a metastatic colon tumor cell as classified in for example, Class 435 subclass 6.

VI. Claims 14-17, drawn to a method of suppressing or inhibiting a cancerous phenotype by administering an antisense polynucleotide as classified in for example, Class 435, subclass 6, and Class 514, subclass 44.

VII. Claims 18-20, drawn to a method of inhibiting tumor growth by administering an agent to a subject having a certain gene being expressed as classified in for example, Class 514, subclass 44.

VIII. Claims 22-29, drawn to a method of identifying a gene product as a target by contacting a candidate gene product with an antisense oligonucleotide as classified in for example, Class 514, subclass 44.

IX. Claims 27 and 30, drawn to a method for identifying agents that decrease biological activity by contacting a candidate agent with a differentially expressed polypeptide gene product as classified for example in Class 514, subclass 2.

X. Claims 31, 34, 37, 38, and 42, 32 and 33, and 39, 40, and 41drawn to different polynucleotide sequences, recombinant host cells, polynucleotide arrays, and pharmaceutical composition comprising a polynucleotide classified in Class 435, subclass 69.1, Class 514, subclass 44, and Class 435 subclass 287.2.

XI. Claim 35, drawn to an isolated polypeptide as classified in Class 530, subclass 350.

XII. Claim 36, drawn to an antibody as classified in Class 530, subclass 387.

2. The inventions are distinct, each from the other because of the following reasons:

a. Inventions I-IX are drawn to patentably distinct methods that involve different method steps, include different reagents and have different objectives. Invention I involves detecting a cancerous cell using a polynucleotide. The invention of Group II is drawn to a method of detecting a cancerous cell using a polypeptide. Group III is drawn to a method of detecting a cancerous cell by using a nucleotide-based array. Group IV is drawn to a method of identifying a cancerous colon cell be detecting a differentially expressed polypeptide in array format. Group V drawn to a method of detecting differentially expressed gene product in order to discern the metastatic ability of the cell. Group VI is drawn to a method of suppressing or inhibiting a

cancerous phenotype by administering an antisense polynucleotide. Group VII is drawn to a method of inhibiting tumor growth through administration of an agent. Group VIII is drawn to a method of identifying a gene product as a target by contacting a candidate gene product with an antisense oligonucleotide. Finally, Group IX is drawn to a method for identifying agents that decrease biological activity by contacting a candidate agent with a differentially expressed polypeptide. The methods all have different method steps, objectives and reagents. Therefore the methods are distinct over one another.

b. Inventions I and X, VI and X, and VIII and X, III and X and VII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of invention can be used in a materially different process such as for protein synthesis.

c. Inventions II and XII and IX and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of invention XII can be used in a materially different process such as for generating antibodies.

d. Inventions X and II, X and IV, X and V, and X and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the nucleic acids of invention X are not required to practice the methods of inventions II, III, IV, V, VII, and IX involving polypeptides.

e. Inventions XII and I, XII and III, XII and IV, XII and V, XII and VI, XII and VII, and XII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the polypeptides of invention XII are not required to practice the methods of inventions I, III-VIII involving different biomolecules.

f. Inventions X and XI are patentably distinct in structure and physiochemical properties. Invention X is drawn to nucleic acids whereas invention XI is drawn to proteins. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the compositions are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while the proteins may be utilized in ligand binding assays or to generate antibodies. The protein of invention XI does not require the particular products of the nucleic acids of group X since the proteins of invention XI can be isolated from natural sources or chemically synthesized.

g. Inventions X and XII are patentably distinct in structure and physiochemical properties. Invention X is drawn to nucleic acids whereas invention XII is drawn to antibodies. Because nucleic acids are composed of nucleotides and antibodies are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the compositions

are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while the antibodies may be utilized in assays to detect the presence or absence of a protein. The nucleic acids of invention X are not required to obtain the antibodies of invention XII.

Restriction Requirement Applicable to All Groups:

3. Each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differs in structure and in function and in biological activity. A restriction is applied to each Group. For an elected Group drawn to a nucleotide sequence, the Applicants must elect a single nucleic acid sequence from "SEQ ID NOS: 1, 3, 5, 7, 9, 11-13, 15, 16, 18, 20, 22, 24, 26, 27 and 29", a single polypeptide encoded by the aforementioned sequences, and a single antibody that specifically binds a single polypeptide (See MPEP 803.04). Furthermore, with respect to the arrays, a single sequence may be elected for use with the array. Similarly, with election of Group I only the single elected sequence will characterize all nucleotide components within the Group, ie, pharmaceutical composition, array, host cell, etc. will include the same elected SEQ ID NO:X.

The search of the selected sequence may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. Similarly, proteins comprising unique amino acid sequences are structurally and functionally distinct. These sequences are thus deemed to

normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter and because these inventions require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Friday from 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W.Gary Jones, can be reached on (703)308-1152. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (703)605-1237.

Sally Gabrin
11/25/02

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER